

CLAIMS

1. A method of determining the presence or absence of abnormally proliferating cells or cellular growth abnormality
5 in a sample from an individual, the method including detecting in the sample a target polypeptide, wherein the target polypeptide is a member of the preinitiation complex of DNA replication;

with the proviso that where the target polypeptide is
10 MCM7 the sample is not the subject of antigen retrieval or pressure cooking/autoclaving.

2. A method according to claim 1 wherein the target polypeptide is selected from the group consisting of CDC6,
15 MCM2, MCM3, MCM4, MCM5, MCM6, MCM7, Cdc7 protein kinase, Dbf4, Cdc14 protein phosphatase, Cdc45, and MCM10.

3. A method according to claim 2 wherein the target polypeptide is selected from the group consisting of CDC6,
20 MCM2, MCM3, MCM4, MCM5, MCM6 and MCM7.

4. A method according to claim 3 wherein the target polypeptide is CDC6.

25 5. A method according to claim 3 wherein the target polypeptide is MCM2.

6. A method according to claim 3 wherein the target polypeptide is MCM3.

7. A method according to claim 3 wherein the target polypeptide is MCM4.

8. A method according to claim 3 wherein the target
5 polypeptide is MCM5.

9. A method according to claim 3 wherein the target polypeptide is MCM6.

10 10. A method according to claim 3 wherein the target polypeptide is MCM7.

11. A method according to claim 1 wherein the method includes contacting the sample with a specific binding member or
15 specific binding members directed against a target polypeptide and determining binding of the specific binding member or members to the sample.

12. A method according to claim 3 wherein the method includes
20 contacting the sample with a specific binding member or specific binding members directed against a target polypeptide and determining binding of the specific binding member or members to the sample.

25 13. A method according to claim 4 wherein the method includes contacting the sample with a specific binding member or specific binding members directed against a target polypeptide and determining binding of the specific binding member or members to the sample.

14. A method according to claim 5 wherein the method includes contacting the sample with a specific binding member or specific binding members directed against a target polypeptide and determining binding of the specific binding member or 5 members to the sample.

15. A method according to claim 6 wherein the method includes contacting the sample with a specific binding member or specific binding members directed against a target polypeptide 10 and determining binding of the specific binding member or members to the sample.

16. A method according to claim 7 wherein the method includes contacting the sample with a specific binding member or 15 specific binding members directed against a target polypeptide and determining binding of the specific binding member or members to the sample.

17. A method according to claim 8 wherein the method includes 20 contacting the sample with a specific binding member or specific binding members directed against a target polypeptide and determining binding of the specific binding member or members to the sample.

25 18. A method according to claim 9 wherein the method includes contacting the sample with a specific binding member or specific binding members directed against a target polypeptide and determining binding of the specific binding member or members to the sample.

19. A method according to claim 10 wherein the method includes contacting the sample with a specific binding member or specific binding members directed against a target polypeptide and determining binding of the specific binding member or members to the sample.

20. A method according to claim 11 wherein said specific binding member is or specific binding members are directed against a plurality of said target polypeptides.

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21. A method according to claim 1 wherein a sample of tissue is tested.

22. A method according to claim 3 wherein a sample of tissue is tested.

23. A method according to claim 21 wherein the sample of tissue is fresh or frozen.

20 24. A method according to claim 22 wherein the sample of tissue is fresh or frozen.

25. A method according to claim 21 wherein the sample of tissue is not formalin fixed or paraffin embedded.

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26. A method according to claim 22 wherein the sample of tissue is not formalin fixed or paraffin embedded.

27. A method according to claim 21 wherein the sample of

tissue is not the subject of antigen retrieval or pressure cooking/autoclaving.

28. A method according to claim 22 wherein the sample of
5 tissue is not the subject of antigen retrieval or pressure cooking/autoclaving.

29. A method according to claim 21 wherein the tissue is
selected from lung, breast, colon, prostate, stomach, skin,
10 oesophagus and bladder.

30. A method according to claim 22 wherein the tissue is
selected from lung, breast, colon, prostate, stomach, skin,
oesophagus and bladder.

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31. A method according to claim 23 wherein the tissue is
selected from lung, breast, colon, prostate, stomach, skin,
oesophagus and bladder.

20 32. A method according to claim 24 wherein the tissue is
selected from lung, breast, colon, prostate, stomach, skin,
oesophagus and bladder.

33. A method according to claim 21 wherein the tissue is
25 breast tissue.

34. A method according to claim 22 wherein the tissue is
breast tissue.

35. A method according to claim 23 wherein the tissue is breast tissue.

36. A method according to claim 24 wherein the tissue is breast tissue.

37. A method according to claim 1 wherein a sample of cells is tested.

38. A method according to claim 3 wherein a sample of cells is tested.

39. A method according to claim 1 wherein the sample is provided from fluid taken from the individual.

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40. A method according to claim 3 wherein the sample is provided from fluid taken from the individual.

41. A method according to claim 39 wherein a sample of cells is provided from said fluid.

42. A method according to claim 40 wherein a sample of cells is provided from said fluid.

43. A method according to claim 39 wherein the fluid is blood.

44. A method according to claim 40 wherein the fluid is blood.

45. A method according to claim 39 wherein the fluid is urine.

46. A method according to claim 40 wherein the fluid is
5 urine.

47. A method according to claim 1 wherein a population of individuals is screened.

10 48. A method according to claim 47 wherein individuals are categorised as having tissue which is (i) normal or (ii) abnormal including potentially or actually pre-cancerous or cancerous, dysplastic or neoplastic cells.

15 49. A method according to claim 48 wherein tissue or cells of individuals categorised as having abnormal tissue are subject to further investigation or analysis.

50. A method of determining the presence or absence of
20 abnormally proliferating cells or cellular growth abnormality
in a cervical sample from an individual, the method including
contacting the sample with a specific binding member or
specific binding members directed against a target polypeptide
and determining binding of the specific binding member or
25 members to the sample, wherein the target polypeptide is a
member of the preinitiation complex of DNA replication.

51. A method according to claim 50 wherein the sample is a cervical smear.

52. A method according to claim 50 wherein the target polypeptide is selected from the group consisting of CDC6, MCM2, MCM3, MCM4, MCM5, MCM6, MCM7, Cdc7 protein kinase, Dbf4, Cdc14 protein phosphatase, Cdc45, and MCM10.

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53. A method according to claim 52 wherein the target polypeptide is selected from the group consisting of CDC6, MCM2, MCM3, MCM4, MCM5, MCM6 and MCM7.

10 54. A method according to claim 53 wherein the target polypeptide is Cdc6.

55. A method according to claim 53 wherein the target polypeptide is MCM2.

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56. A method according to claim 53 wherein the target polypeptide is MCM3.

57. A method according to claim 53 wherein the target
20 polypeptide is MCM4.

58. A method according to claim 53 wherein the target polypeptide is MCM5.

25 59. A method according to claim 53 wherein the target polypeptide is MCM6.

60. A method according to claim 53 wherein the target polypeptide is MCM7.

61. A method according to claim 53 wherein the sample is a cervical smear.

62. A method according to claim 50 wherein said specific
5 binding member is or specific binding members are directed against a plurality of said target polypeptides.

63. A method according to claim 62 wherein the sample is a cervical smear.

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64. A method according to claim 50 wherein a population of individuals is screened.

65. A method according to claim 64 wherein individuals are
15 categorised as having tissue which is (i) normal or (ii) abnormal including potentially or actually pre-cancerous or cancerous, dysplastic or neoplastic cells.

66. A method according to claim 65 wherein tissue or cells of
20 individuals categorised as having abnormal tissue are subject to further investigation or analysis.

67. A method of determining the presence or absence in an individual of abnormally proliferating cells or cellular
25 growth abnormality, the method including detecting a target polypeptide, or mRNA encoding a target polypeptide, in tissue, fluid or cells of an individual, wherein the target polypeptide is a member of the preinitiation complex of DNA replication;

with the proviso that where the method is carried out on a sample removed from the individual and the target polypeptide is MCM7 the sample is not the subject of antigen retrieval or pressure cooking/autoclaving.

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68. A method according to claim 67 wherein said tissue, fluid or cells are in a sample removed from the individual.

69. A method according to claim 68 wherein said sample is of
10 tissue.

70. A method according to claim 69 wherein the sample is fresh or frozen.

15 71. A method according to claim 69 wherein the sample is not formalin fixed or paraffin embedded.

72. A method according to claim 69 wherein the sample of tissue is not the subject of antigen retrieval or pressure
20 cooking/autoclaving.

73. A method according to claim 67 wherein a population of individuals is screened.

25 74. A method according to claim 73 wherein individuals are categorised as having tissue which is (i) normal or (ii) abnormal including potentially or actually pre-cancerous or cancerous, dysplastic or neoplastic cells.

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75. A method according to claim 74 wherein tissue or cells of individuals categorised as having abnormal tissue are subject to further investigation or analysis.

5 76. A kit including a specific binding member or specific binding members directed against one or more target polypeptides, wherein a target polypeptide is a member of the preinitiation complex of DNA replication, and instructions for use of the specific binding member or members in a method
10 according to any of claims 11 to 48.

77. A kit according to claim 76 wherein the target polypeptide is selected from the group consisting of CDC6, MCM2, MCM3, MCM4, MCM5, MCM6, MCM7, Cdc7 protein kinase, Dbf4,
15 Cdc14 protein phosphatase, Cdc45, and MCM10.

78. A kit according to claim 77 wherein the target polypeptide is selected from the group consisting of CDC6, MCM2, MCM3, MCM4, MCM5, MCM6 and MCM7.

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79. A kit according to claim 78 wherein the target polypeptide is CDC6.

80. A kit according to claim 78 wherein the target
25 polypeptide is MCM2.

81. A kit according to claim 78 wherein the target polypeptide is MCM3.

82. A kit according to claim 78 wherein the target polypeptide is MCM4.

83. A kit according to claim 78 wherein the target
5 polypeptide is MCM5.

84. A kit according to claim 78 wherein the target polypeptide is MCM6.

10 85. A kit according to claim 78 wherein the target polypeptide is MCM7.

86. A kit according to any of claims 71 wherein said specific binding member is or specific binding members are directed
15 against a plurality of said target polypeptides.

87. A kit according to any of claims 73 wherein said specific binding member is or specific binding members are directed against a plurality of said target polypeptides.